In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

Filed: March 29, 2022

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AMANDA SWINT-MOORE *and* MICHAEL MOORE, *as Parents and Next Friends of* M.A.M., *a minor,*	*	No. 18-1112V
Petitioners,	*	Special Master Sanders
v.	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	Motion to Dismiss; Diphtheria-Tetanus-Acellular Pertussis ("DTaP"); Haemophilus Influenza Type B ("HiB"); Pneumococcal Conjugate ("PCV") Vaccines; DYRK1A Mutation; Seizures; Development Delay
Respondent.	*	
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Forrest E. Jackson, Jackson Law Firm, PLLC, Chattanooga, TN, for Petitioners.
Debra A. Filteau Begley, U.S. Department of Justice, Washington, DC, for Respondent

ORDER DENYING MOTION TO DISMISS[1]

On July 30, 2018, Amanda Swint-Moore and Michael Moore ("Petitioners") filed a petition for compensation under the National Vaccine Injury Compensation Program,[2] alleging that M.A.M., a minor in their care, developed, or suffered a significant aggravation of, seizures and/or developmental delay as a result of the haemophilus influenza type B ("HiB"), pneumococcal conjugate ("PCV"), and diphtheria-tetanus-acellular pertussis ("DTaP") vaccines she received on July 30, 2015. Pet. at 1, ECF No. 1. On September 16, 2019, Respondent filed a motion to dismiss asserting that "it is undisputed that M.A.M.'s alleged injuries were caused by her known and recognized DYRK1A genetic mutation[]" and consequently, "[P]etitioners cannot establish

[1] This Order will be posted on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 (2012). **This means the Order will be available to anyone with access to the internet**. As provided by 42 U.S.C. § 300aa-12(d)(4)(B), however, the parties may object to the Order's inclusion of certain kinds of confidential information. Specifically, under Vaccine Rule 18(b), each party has fourteen days within which to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the Order in its present form will be available. *Id.*

[2] The Vaccine Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3758, codified as amended at 42 U.S.C. §§ 300aa-10 through 34 (2012) ("Vaccine Act" or "the Act"). Individual section references hereafter will be to § 300aa of the Act (but will omit that statutory prefix).

entitlement to compensation." Resp't's Mot. at 1, ECF No. 23. Petitioners counter in their opposition to Respondent's motion, that "[w]hile M.A.M. was subsequently diagnosed with the DYRK1A genetic mutation, she had never experienced any seizures prior to [her] vaccinations, and any developmental delays that may have presented prior to that date were [therefore] exacerbated and worsened after these vaccinations." Pet'r's Opp'n at 6, ECF No. 25. Petitioners contend that "the record supports a finding that M.A.M.'s [condition was] caused by and/or significantly aggravated by her July 30, 2015 vaccinations." *Id.*

After a careful consideration of the evidence that has been filed thus far, I find that Petitioners cannot be summarily disqualified from the Program based solely on the presence of M.A.M.'s genetic mutation. This Order does not reach the issue of causation. However, Petitioners will be afforded the opportunity to present evidence of a biological mechanism that considers M.A.M.'s mutation in its explanation of causality. Respondent's motion to dismiss is therefore **DENIED**.

I. Summary of Medical Records

A. Pre Vaccination

M.A.M. was born on January 4, 2014. Pet'r's Ex. 3 at 1, ECF No. 1-4. On February 7, 2014, M.A.M. was seen for her one-month well-child visit. *Id.* at 2. During this visit, Petitioners expressed concern that M.A.M. was frequently spitting up, and she was diagnosed with acid reflux.[3] *Id.* During M.A.M.'s two-month well-child visit on March 7, 2014, she weighed 10.7 pounds, she was 21.5 inches long, and her head circumference was 14.25 inches. *Id.* at 3. M.A.M. received her DTaP, HiB, PCV, and inactivated polio ("IPV") vaccinations. *Id.* Petitioners reported that M.A.M. was still spitting up after every feeding, so she was referred to a gastrointestinal specialist for her acid reflux. *Id.*

M.A.M. underwent a swallowing study on April 15, 2014, which revealed severe dysphagia[4] with silent aspiration[5] of both thick and thin feeds. *Id.* As a result, M.A.M. was admitted to the hospital for insertion of a feeding tube. *Id.* After discharge, Petitioners asked for a second opinion, so she was re-admitted for further evaluation on April 29, 2014. *Id.* During her hospital stay, a second swallowing study showed no aspiration, so M.A.M.'s feeding tube was removed, and she was discharged home with a diagnosis of acid reflux. *Id.* at 19.

At M.A.M.'s four-month evaluation on May 20, 2014, she weighed 14.1 pounds, was 24.5 inches long, and her head circumference was 15.25 centimeters. *Id.* at 4. During a developmental assessment, M.A.M. was unable to roll over from her stomach to her back. Pet'r's Ex. 24 at 38, ECF No. 20-16. She received the DTaP, HiB, PCV, and IPV vaccinations. Pet'r's Ex. 3 at 4. During her six-month well-child visit on July 29, 2014, M.A.M. met most of her developmental

[3] Acid reflux is also referred to as gastroesophageal reflux disease ("GERD"). GERD is "any condition noted clinically or histopathologically that results from gastroesophageal reflux, ranging in seriousness from mild to life-threatening; principal characteristics are heartburn and regurgitation." *Dorland's Illustrated Medical Dictionary* 1, 533 (32nd ed. 2012) [hereinafter "*Dorland's*"].

[4] Dysphagia is "difficulty in swallowing." *Dorland's* at 579.

[5] Aspiration is "the drawing of a foreign substance into the respiratory tract during inhalation." *Dorland's* at 166.

milestones. Pet'r's Ex. 24 at 38. She received the DTaP, HiB, PCV, and IPV vaccines. Pet'r's Ex. 3 at 5. M.A.M. was seen for her nine-month visit on October 7, 2014. *Id.* at 6; Pet'r's Ex. 24 at 28. On that date, M.A.M. met some developmental milestones, and she showed no anxiety to strangers. *Id.* at 38. M.A.M. received a Hepatitis B vaccination. Pet'r's Ex. 3 at 6.

On January 16, 2015, M.A.M. was treated for a fever and her rapid test for streptococcus ("strep") was positive. Pet'r's Ex. 24 at 27. Two weeks later, on January 30, 2015, M.A.M. presented for her twelve-month well-child visit. *Id.* at 26. During this visit, she weighed 22.12 pounds, she was 30 inches long, and her head circumference was 17 centimeters. *Id.* Her pediatrician noted that M.A.M. could not say two- to- four words, and he assessed M.A.M. with "abnormal" development. *Id.* M.A.M. again tested positive after a rapid test for strep. *Id.* She received the measles, mumps, and rubella ("MMR") and varicella vaccines at this visit. *Id.*

On February 11, 2015, M.A.M. was brought to her pediatrician for a one-day history of a red rash over her entire body. *Id.* at 25. A third rapid strep test was also positive. *Id.* Her pediatrician assessed M.A.M. with a "post[-]vaccine measles rash," and streptococcal pharyngitis.[6] *Id.* On February 23, 2015, M.A.M. was evaluated for red cheeks and a fever, and she was assessed with recurrent streptococcal pharyngitis after a fourth positive rapid strep test. *Id.* at 24. On July 30, 2015, M.A.M. underwent an eighteen-month evaluation. *Id.* at 21. She weighed 28.8 pounds, she was 32 inches long, and her head circumference was 17.5 centimeters. *Id.* Her pediatrician documented an abnormal developmental screen, but a normal autism screen. *Id.* M.A.M.'s mother also expressed concern about M.A.M.'s development. *Id.* M.A.M. received the Hepatitis A, DTaP, HiB, PCV, and IPV vaccines. *Id.*

B. Post Vaccination

The day following vaccination, on July 31, 2015, Petitioners took M.A.M. to her pediatrician following a febrile seizure[7] at 2:30 am that morning. *Id.* at 20. M.A.M. had a second seizure while in the pediatrician's office and was diagnosed with an ear infection and a febrile seizure. *Id.* Her pediatrician prescribed antibiotics. *Id.* Petitioners brought M.A.M. to the emergency room later that same day after she suffered another febrile seizure. Pet'r's Ex. 10 at 88, ECF No. 20-1. M.A.M.'s father described her history of seizures to the emergency room physician. *Id.* He stated that in between these events, M.A.M. was walking, playing with a kitten, and snacking (although her food intake was "not great"). *Id.* The attending physician noted that she had a droopy right eyelid that Petitioners said had been present since birth. *Id.* Testing was again positive for a strep infection. *Id.* at 90. She was admitted for further evaluation. *Id.* at 92. An EEG revealed a "mild abnormality," inconsistent with epilepsy.[8] *Id.* at 93. M.A.M. was treated with

[6] Streptococcal pharyngitis is commonly known as strep throat. It is defined as "an acute variety caused by infection with *Streptococcus pyogenes;* it occurs in epidemics and is usually spread by droplets or in air, although it can also be spread by direct contact and in food. Characteristics include intense local hyperemia, sometimes with enlargement of cervical lymph nodes and a yellow exudate." *Dorland's* at 1426.

[7] A febrile seizure is a convulsion associated "with high fever, usually seen in infants and children." *Dorland's* at 411, 1688.

[8] Epilepsy is "any of a group of syndromes characterized by paroxysmal transient disturbances of the brain function that may be manifested as episodic impairment or loss of consciousness, abnormal motor phenomena, psychic or sensory disturbances, or perturbation of the autonomic nervous system." *Dorland's* at 633.

Keppra.[9] *See* Pet'r's Ex. 4, ECF No. 1-5. She was discharged on August 1, 2015, with a diagnosis of streptococcal pharyngitis and febrile seizures, which were "resolved." Pet'r's Ex. 10 at 92. On August 24, 2015, Petitioners reported to M.A.M.'s pediatrician that she had not had any further seizures, and an examination of her ears and throat was normal. Pet'r's Ex. 24 at 19.

On September 23, 2015, M.A.M. was evaluated by neurologist, Karsten Gammeltoft, M.D., for "brief spells lasting perhaps [one] minute during which [M.A.M.] would appear sluggish with a fine tremor[.]" Pet'r's Ex. 4 at 10. Dr. Gammeltoft concluded that M.A.M.'s spells were "not particularly suggestive of focal seizures[,]" and her response to "Keppra may be incidental." *Id.* at 12. Dr. Gammeltoft further concluded that there was "little evidence of actual epilepsy," so she discontinued M.A.M.'s use of Keppra. *Id.*

On December 25, 2015, M.A.M. suffered another seizure and was seen at the hospital. Pet'r's Ex. 3 at 21. She was placed back on Keppra and Diazepam.[10] *Id.* During a January 6, 2016 follow-up visit with M.A.M.'s pediatrician, Petitioners explained that M.A.M. had developed nasal congestion and exhibited "staring spells" that morning. *Id.* A rapid strep test was again positive. *Id.* M.A.M.'s pediatrician increased her dosage of Keppra and prescribed antibiotics. *Id.*

During a two-year assessment on January 11, 2016, M.A.M. was assessed with a speech delay. *Id.* at 22; Pet'r's Ex. 24 at 38. She was unable to use at least twenty words or use two-word phrases. Pet'r's Ex. 24 at 39. On February 11, 2016, M.A.M. saw Christopher Miller, M.D., a neurologist. Pet'r's Ex. 22 at 35, ECF No. 20-13. Upon examination, Dr. Miller noted that M.A.M.'s head circumference was low at 45 cm. *Id.* He was unable to discern any clear words and noted that M.A.M. had mildly low tone. *Id.* Dr. Miller noted that M.A.M. engaged in some "very unusual behaviors, such as licking the floor and rolling around on the floor." *Id.* Dr. Miller observed that M.A.M. had an "unusual constellation of microcephaly,[11] significant language delays, and apparent partial complex seizures," and he ordered an MRI for further evaluation. *Id.* M.A.M. underwent an MRI on March 3, 2016, and it revealed "low-normal white matter volume[.]" *Id.* at 41.

During a return visit to Dr. Miller on April 12, 2016, he noted that M.A.M.'s MRI revealed underdevelopment or dysmyelination of white matter that "is related to her developmental lag." *Id.* at 29. He noted that while M.A.M. had made some progress with her speech, she remained significantly speech delayed. *Id.* M.A.M., he further noted, had remained "seizure-free" while on Keppra. *Id.* She remained "relatively microcephalic with a head circumference of 45.5 cm," and her ambulation was "mildly clumsy." *Id.* A repeat MRI was scheduled for later that year. *Id.*

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[9] Keppra is the "trademark for a preparation of levetiracetam." *Dorland's* at 978. Levetiracetam is "an anticonvulsant administered orally as an adjunct in the treatment of partial and myoclonic seizures and idiopathic generalized epilepsy." *Id.* at 1031.

[10] Diazepam is "a benzodiazepine used as an antianxiety agent in the treatment of anxiety disorders and for short-term relief of anxiety symptoms, as a preoperative or preprocedural medication to relieve anxiety and tension, also as a skeletal muscle relaxant, anticonvulsant, antitremor agent, antipanic agent, and for treatment of symptoms of acute alcohol withdrawal; administered orally, rectally, intravenously, or intramuscularly." *Dorland's* at 512.

[11] Microcephaly is "abnormal smallness of the head, usually associated with intellectual disability." *Dorland's* at 1157.

An MRI performed on September 29, 2016, revealed persistent "low-normal white matter volume, not significantly changed from the previous study," and a "T2-signal within the periventricular white matter[.]" *Id.* at 39. During a follow-up with Dr. Miller on October 13, 2016, he noted that M.A.M. remained seizure-free while on Keppra. *Id.* at 25. However, she remained "fairly significantly delayed." *Id.* M.A.M.'s head measurements remained in the microcephalic range, and her facial features were "moderately dysmorphic." *Id.* He noted that her speech was "largely unrecognizable," but she had a normal tone and gait. *Id.* Dr. Miller referred M.A.M. to a genetics specialist for "their thoughts on her phenotype." *Id.*

In January 2017, M.A.M. underwent a psychological evaluation. Pet'r's Ex. 19 at 4, ECF No. 20-10. She was not diagnosed with autism, but she was diagnosed with an intellectual disability with deficits in communication, adaptive behavior, and cognitive skills. *Id.*

On February 9, 2017, M.A.M. was evaluated by Jared Hamm, M.D., a geneticist. Pet'r's Ex. 21 at 23, ECF No. 20-12. M.A.M.'s mother reported to Dr. Hamm that M.A.M. was meeting her developmental milestones until she was eighteen months old and developed febrile seizures "associated with receipt of vaccines." *Id.* She also reported "another febrile seizure shortly thereafter associated with an infectious illness." *Id.* Her mother explained that after the seizures began, M.A.M.'s language has stalled and that "there may have been some regression[,]" as she had "[five- to- ten] words at [eighteen] months and now only consistently has about [four]." *Id.* Dr. Hamm noted a possible autism diagnosis, "based on her speech delay, toe walking, hand clapping, and other characteristic behaviors." *Id.* Upon examination, Dr. Hamm observed that M.A.M. was microcephalic, had prominently turned-out ears, and "slightly up[-]slanting palpebral fissures."[12] *Id.* at 25. Dr. Hamm's assessment of M.A.M. included autism and seizure disorder, and he ordered genetic testing. *Id.* at 27. A chromosomal microarray performed in February of 2017 was normal and testing for Rett syndrome[13] was negative. Pet'r's Ex. 10 at 47, 49, ECF No. 20-1.

Additional testing performed in April of 2017 revealed that M.A.M. has a genetic mutation known as DYRK1A. Pet'r's Ex. 6 at 2, ECF No. 9. The test report explained that this mutation "has been classified as likely pathogenic," and is "associated with the clinical features seen in this patient[.]" *Id.* It further explained that this mutation is associated with "autosomal dominant mental retardation," and patients with this variant are known to display "seizures, intellectual disability, delayed or impaired language development, autistic behaviors, microcephaly, large ears, and deep-set eyes." *Id.*

During a follow-up visit to Dr. Hamm on October 16, 2017, he explained that M.A.M. had a DYRK1A abnormality, that is a "heterozygous de novo likely pathogenic variant," that has been associated with "seizures, intellectual disability, autism, and dysmorphic features." Pet'r's Ex. 21 at 5. Dr. Hamm noted his belief that this mutation "is causative for [M.A.M.'s] clinical

[12] Palpebral fissures refer to the "longitudinal opening between the eyelids." *Dorland's* at 1647.

[13] Rett syndrome is "a pervasive developmental disorder affecting the gray matter of the brain, occurring exclusively in females and present from birth; it is progressive and is characterized by autistic behavior, ataxia, dementia, seizures, and loss of purposeful use of the hands, with cerebral atrophy, mild hyperammonemia, and decreased levels of biogenic amines. It is an X-linked dominant disorder caused by a loss-of-function mutation in the *MEP2* gene, which encodes a methyl-CpG-binding protein that regulates transcription of other genes." *Dorland's* at 1846.

symptoms[.]" *Id.* M.A.M. continued to have occasional breakthrough seizures through 2019, while in the care of Dr. Miller. Pet'r's Ex. 22 at 9, 13, 17. She received regular speech and occupational therapy, but continued to show evidence of microcephaly and severely limited speech. *Id.* at 9.

II. Procedural History and Parties' Arguments

A. Procedural History

Along with their petition, Petitioners filed five medical record exhibits on July 30, 2018, in support of their claim. Pet'r's Exs. 1–5, ECF Nos. 1-1–1-6. Petitioners filed personal affidavits and additional medical records on November 13, 2018. Pet'r's Exs. 6–9, ECF Nos. 9–11, 15. Petitioners also filed a statement of completion on that date. ECF No. 13. Thereafter, on February 19, 2019, Respondent filed a status report, in which he identified outstanding medical records needed to evaluate Petitioners' claim. ECF No. 16. In response, Petitioners filed several additional medical record exhibits on April 15, 2019. Pet'r's Exs. 10–34, ECF Nos. 20-1–20-25.

Respondent filed his Rule 4(c) report on July 5, 2019, in which he asserted that "the petition for compensation in this case should be dismissed." Resp't's Report at 11, ECF No. 22. In support of this argument, Respondent referred to "the overwhelming evidence pointing to M.A.M.'s known genetic disorder as the cause of her symptoms," and concluded that "it is extremely unlikely that [P]etitioners could establish that M.A.M.'s July 30, 2015 vaccinations, played any role in causing her condition." *Id.* Respondent cited the medical records, which state that M.A.M.'s "mutation 'has been classified as likely pathogenic,' and is 'associated with the clinical features seen in this patient[.]'" *Id*. (citing Pet'r's Ex. 6 at 2). Respondent immediately followed his Rule 4(c) report with a motion to dismiss, filed on September 16, 2019. ECF No. 23.

B. Respondent's Motion to Dismiss

Respondent asserts that Petitioners' petition must be dismissed because "[t]he undisputed facts in this case make clear that [P]etitioners cannot establish their burden under *Althen."* Resp't's Mot. at 7. This case, similar to numerous other unsuccessful Program cases that involve a child with a "genetically mediated seizure disorder," argues that "a post vaccination increase in seizure activity otherwise attributable to an underlying genetic condition can be deemed a vaccine-caused significant aggravation." *Id.* Respondent argues that in at least sixteen previous cases, "special masters have concluded that even a vaccine-triggered transient negative response in an individual with an underlying condition has not been deemed proof of worsening if that individual would be expected to experience a similar course regardless." *Id.* at 7–8 (citing *Sharpe v. Sec'y of Health & Hum. Servs.,* No. 14-65V, 2018 WL 7625360 at *26 (Fed. Cl. Spec. Mstr. Nov. 5, 2018)).

Respondent additionally argues that even if M.A.M.'s febrile seizures were caused by her vaccinations, Petitioners' claim fails because, "there is no evidence that her initial seizures caused any worsening of her condition when compared to the expected outcome for children with a DYRK1A mutation." Resp't's Mot. at 9. In addition to seizures, a DYRK1A mutation phenotype can include "developmental delay, autism-like behavior, and dysmorphic features." *Id.* Respondent further argues that M.A.M. was exhibiting other features consistent with the DYRK1A mutation prior to vaccination and Petitioners submitted "no evidence that M.A.M.'s onset of

seizures at eighteen months of age is in any way inconsistent with a DYRK1A." *Id.* at 10. Therefore, Respondent argues, "it is extremely unlikely that [P]etitioners could establish that [M.A.M.'s vaccinations] played any role in causing her condition." *Id.*

Respondent filed a reply to Petitioners' opposition to Respondent's motion to dismiss on October 15, 2019. Resp't's Reply, ECF No. 26. In Respondent's reply, he asserts that Petitioners' additional filings "provide no new evidence that establishes [P]etitioners' burden under the Act." *Id.* at 1. First, Respondent argues that M.A.M.'s treating physician pointed to her genetic mutation as causal for all of her symptoms. *Id.* at 2. Next, Respondent argues that even if M.A.M could establish a connection between her vaccinations and febrile seizures, no other seizures or "other events occurred in close proximity to her vaccinations." *Id.* at 3. Lastly, Respondent notes that Petitioners have not presented any evidence of a biological mechanism, including applicability to M.A.M.'s case or an appropriate temporal relationship between vaccination and symptom manifestation. *Id.* at 4.

On April 16, 2021, Respondent filed a supplemental reply to the Petitioners' response. ECF No. 33. He again asserts that Petitioners "provide no new evidence that establishes Petitioners' burden under the Act." *Id.* at 1. Respondent argues that the letter from M.A.M.'s treater establishes that her seizures are "likely related to her known genetic condition." *Id.* at 2. M.A.M.'s treater also concedes, "it is likely that those individuals [with this genetic mutation] would go on to develop seizures at some point in time anyway." *Id.* He reiterates his previous argument that Petitioner has no biological mechanism that connects M.A.M.'s vaccination and alleged injury and requests dismissal. *Id.* at 6.

C. Petitioners' Opposition

Petitioners filed an opposition to Respondent's motion to dismiss, along with an expert report from M.A.M.'s treater, Scout Robinson, M.D., on September 30, 2019. Pet'r's Opp'n, ECF Nos. 24–25. They highlight the treating physician's comment that "it is reasonable to conclude that the inflammatory response from these vaccinations "ignited or triggered seizure activity in M.A.M." Pet'r's Opp'n at 2. Petitioners also note that Respondent's argument against causation relies on evidence relating to a different genetic mutation than the one in the present case. *Id.* at 5–6. Petitioners argue that M.A.M.'s condition was not a foregone conclusion based on her genetic mutation. *Id.* at 4, 6. Alternatively, Petitioners argue there is sufficient evidence for a significant aggravation claim. *Id.* at 6.

Following Respondent's reply to Petitioners' opposition, I deferred ruling on Respondent's motion to dismiss and ordered Petitioners to submit an expert report. Non-PDF Order, docketed May 5, 2020. Petitioners filed several motions for extension of time throughout 2020, and on December 18, 2020, Petitioners filed a second expert report from Dr. Miller, M.A.M.'s treating physician, along with supporting documentation. ECF No. 31. Petitioners filed their response to Respondent's supplemental reply on June 3, 2021. ECF No. 34. Petitioners generally reiterated their prior arguments. *Id.*

III. Legal Standard

Although Respondent styled his motion as a motion to dismiss, I am construing it as a motion for summary judgment. The Vaccine Rules allow for a special master to decide a case on summary judgment. *See Jay v. Sec'y of Health & Hum. Servs*., 998 F.2d 70, 82–83 (Fed. Cir. 1992); *see also* Vaccine Rule 8(d) (stating "the special master may decide a case on the basis of written submissions without conducting an evidentiary hearing. Submissions may include a motion for summary judgment, in which event the procedures set forth in RCFC 56 will apply."). Pursuant to RCFC 56, summary judgment is appropriate when "the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." RCFC 56(a). In ruling on a motion to dismiss, like ruling on a motion for summary judgment, special masters must draw every inference concerning disputed facts in favor of the nonmoving party. *See Warfle v. Sec'y of Health & Hum. Servs*., 05-1399V, 2007 WL 760508 at *2 (Fed. Cl. Spec. Mstr. Feb. 22, 2007); *Guilliams v. Sec'y of Health & Hum. Servs*., No. 11-716V, 2012 WL 1145003, at *9–10 (Fed. Cl. Spec. Mstr. Mar. 14, 2012); *Richard v. Sec'y of Health & Hum. Servs*., No. 02-877V, 2010 WL 2766742, at *4–5 (Fed. Cl. Spec. Mstr. May 3, 2010).

The United States Supreme Court has provided guidance on the summary judgment standard in *Anderson* and *Celotex Corp*. *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 244 (1986); *see also Celotex Corp. v. Catrett*, 477 U.S. 317, 322–23 (1986). A dispute is genuine if "the evidence is such that a reasonable [fact finder] could return a verdict for the nonmoving party." *Anderson*, 477 U.S. at 248. A fact is material if it "might affect the outcome of the suit under the governing law." *Id.* The moving party "bears the [burden] of . . . demonstrat[ing] the absence of a genuine issue of material fact." *Celotex Corp.*, 477 U.S. at 323. The burden then shifts to the nonmoving party to "set forth specific facts showing that there is a genuine issue for trial." *Anderson*, 477 U.S. at 256. A showing of "mere denials or conclusory statements [is] not sufficient" to demonstrate genuine disputes. *Mingus Constructors, Inc. v. United States*, 812 F.2d 1387, 1390–91 (Fed. Cir. 1987).

In cases where there are no disputes between the parties with respect to the factual record, Respondent must show entitlement to judgment as a matter of law. In the *Sharpe* case, the Federal Circuit clarified the petitioner's burden pursuant to the *Loving* factors in significant aggravation claims and explained how to apply the *Althen* factors in cases where there is an underlying genetic mutation. *Sharpe v. Sec'y of Health & Hum. Servs.*, 964 F.3d 1072 (Fed. Cir. 2020) (citing *Loving ex rel. Loving v. Sec'y of Health & Hum. Servs*., 86 Fed. Cl. 135 (2009); *Althen v. Sec'y of Health & Hum. Servs.*, 418 F.3d 1274 (Fed. Cir. 2005)). After establishing the petitioner's pre- and post-vaccination conditions, *Loving* prong 3 "requires a comparison of a petitioner's current, post-vaccination condition with her pre-vaccination condition." *Sharpe,* 964 F.3d at 1082. It is not required, however, for "a petitioner to prove her expected outcome and that her post-vaccination condition is worse than this expected outcome[.]" *See id*.

The Circuit further held that "a petitioner may be able to make out a prima facie case under *Loving* prong 4 without eliminating a pre-existing condition as the cause of her significantly aggravated injury." *Id.* at 1083. Pursuant to prong 4, "a petitioner need only provide a 'medical theory causally connecting petitioner's significantly worsened condition to the vaccination.'" *Id.* (citing *Loving,* 86 Fed. Cl. at 144). When Petitioner establishes a prima facie case, "the burden falls on the government under the 'factor unrelated' inquiry to show that the pre-existing condition

caused the significantly worsened condition." *Sharpe,* 964 F.3d at 1083. This standard is consistent with the Program's purpose to "allow the finding of causation in a field bereft of complete and direct proof of how vaccines affect the human body." *Id.* (citing *Althen,* 418 F.3d at 1280). To "allow the government to prevail under the 'factor unrelated' inquiry with mere proof of a gene mutation" would ensure that "children with gene mutations will be shut out from the Vaccine Injury Program." *Sharpe,* 964 F.3d at 1087.

Ultimately, these situations "present[] the difficult but important task of determining whether a child's receipt of vaccinations significantly aggravated her seizure disorder in the face of an underlying genetic mutation." *Id.* This cannot be compounded by "requir[ing] [a petitioner] to disprove that a pre-existing genetic mutation caused her signification aggravation." *Id.*

IV. Discussion

In this case, Respondent filed a motion to dismiss immediately after his Rule 4(c) report. At that time, Petitioners had not yet filed any expert reports. Initially, Respondent's motion did not assert that Petitioners claim should be dismissed because a biological mechanism had not been identified. In Petitioners' opposition to the initial motion, their argument was addressing whether the claim could survive at all in the face of a DYRK1A mutation. The Federal Circuit has condemned outright rejections of vaccination causation in cases with genetic mutations. The Circuit noted in *Sharpe* that "both parties' experts agree that vaccinations can adversely interact with a DYNC1H1 gene mutation," therefore, "the [s]pecial [m]aster's rejection of Petitioner's medical theory was arbitrary and capricious." *Sharpe,* 964 F.3d at 1085. They continued that "[i]t is clear from the record that the [s]pecial [m]aster concluded that [Petitioner] was destined to have a severe outcome." *Id.* at 1084. The Circuit warned that "[t]his deterministic mindset does not belong in the Vaccine Injury Program." *Id.*

Here, Petitioners' claim cannot be summarily dismissed because M.A.M. has a DYRK1A genetic mutation. Petitioners may still be able to establish by a preponderant standard that vaccinations are the but-for cause of M.A.M.'s seizures. Furthermore, for a significant aggravation claim, Petitioners are only required to demonstrate "that a vaccine 'can' cause a significant worsening of [M.A.M.'s] seizure disorder." *See id.* at 1083. Respondent's argument here is the exact argument that was rejected in *Sharpe*. It is likewise unsuccessful here. As a result, there remain genuine disputes of material fact and Respondent is not entitled to judgment as a matter of law.

V. Conclusion

Petitioners must be given the opportunity to submit evidence of a biological mechanism and to articulate how that causation theory is applicable to M.A.M.'s case. This Order therefore does not reach the question of whether any of M.A.M.'s symptoms are the result of her vaccinations. As such, Petitioners must obtain expert(s) and submit expert reports as outlined in my forthcoming scheduling order.

Accordingly, Respondent's motion to dismiss is hereby **DENIED**. Petitioner shall file an expert report and any supporting medical literature as described in Appendix A, **by no later than**

Tuesday, May 31, 2022. Any questions regarding this Order may be directed to my law clerk, Alyssa Murphy, at alyssa_murphy@cfc.uscourts.gov.

IT IS SO ORDERED.

s/Herbrina D. Sanders
Herbrina D. Sanders
Special Master